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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HOSPIRA, INC. and ORION
CORPORATION,

Plaintiffs,
v.

SANDOZ INTERNATIONAL GmbH,
SANDOZ INC., and SANDOZ CANADA INC.

Defendants.

Civil Action No. 3:09-cv-04591-MLC-TJB

Filing Date: September 4, 2009
Judge Mary L. Cooper

REDACTED VERSION

**MEMORANDUM OF LAW IN SUPPORT OF SANDOZ INC.'S
MOTION APPEALING THE MAGISTRATE JUDGE'S
DECEMBER 16, 2010 LETTER ORDER**

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Defendant Sandoz Inc. respectfully submits this memorandum in support of its appeal of the Magistrate Judge's December 16, 2010 Letter Order (D.E.138 ("Letter Order")) effectively denying Sandoz Inc.'s motion to amend its invalidity and non-infringement contentions during this Hatch-Waxman litigation. For the reasons set forth below, Sandoz Inc. respectfully requests that its proposed amendments to its contentions be allowed.

I. INTRODUCTION

On August 16 and 27, 2010, Sandoz Inc. served Plaintiffs with proposed amended invalidity and non-infringement contentions, and sought Plaintiffs' consent to those amendments under Local Patent Rule 3.7. Sandoz Inc. proposed contentions that mirrored those served as of right by Sandoz Canada Inc., a new party added to the case by Plaintiffs in May 2010, for whom the pleadings closed on July 22, 2010. Sandoz Inc. served its proposed amendments before any fact depositions had been taken, before expert reports on invalidity and non-infringement were due, and before a claim construction ruling had issued. The proposed amendments were based on [REDACTED]. Thus, as a matter of efficiency, Sandoz Inc. sought to amend its contentions to conform to those served by Sandoz Canada, at a time when no prejudice could arise for Plaintiffs, so that this case could proceed on the merits.

The Magistrate Judge declined to allow Sandoz Inc. to amend its contentions in any respect unless Sandoz Inc. produced a witness at a hearing to testify to its diligence in seeking leave to amend. As the only witnesses who could testify as to events learned during discovery would be trial counsel, and the required testimony would necessarily risk invading areas of trial strategy and work product, Sandoz Inc. requested that the Magistrate Judge allow it to simply join Sandoz Canada's contentions served as of right. On December 16, 2010, Magistrate Judge Bongiovanni issued a Letter Order stating that such reliance would not be allowed *during* the case, and would only be permitted *after* a judgment was rendered, and then only to the extent

permitted by res judicata or collateral estoppel should Sandoz Canada's contentions win the day. As this order effectively denies Sandoz Inc.'s right to amend its contentions now, despite the lack of prejudice to the Plaintiffs, and places all parties in a state of uncertainty as to the effect of a judgment of invalidity or non-infringement in this case, Sandoz Inc. respectfully appeals.

The unfairness and inefficiency of this result compel reversal. Plaintiffs knew about the references and documents in question [REDACTED] before ever bringing this action, and had they disclosed them to the Patent Office as they were required to do, the patents in suit would never have issued. Several of the documents at issue are confidential to Plaintiffs, and could not have been known to Sandoz Inc. before its initial contentions were served. Moreover, the references and documents at issue will be in the case even with the Magistrate Judge's ruling, because they are included in Sandoz Canada's contentions and at least some are asserted in both Sandoz Inc.'s and Sandoz Canada's claims of inequitable conduct.

Yet, if Plaintiffs have their way, even if their patents are found invalid on this art, Plaintiffs will refuse to accept that judgment without further post-judgment briefing to establish (although there should be no legitimate dispute) that res judicata and collateral estoppel do in fact bind them as against Sandoz Inc. Particularly with the end of the 30-month stay in January 2012, there is no need for the continuing uncertainty and delay this outcome would create. Here, Sandoz Inc.'s proposed amendments merely amplify and expand upon theories it already asserted. Those amendments do not introduce new issues, will be part of the case in any event, and will cause no prejudice. The Hobson's choice imposed on Sandoz Inc. – produce trial counsel for cross-examination, or forego its amendments and risk preclusion at the end of the case – is contrary to law and clearly erroneous. Sandoz Inc.'s contentions should be allowed, or

in the alternative, it should be permitted to rely on the contentions of Sandoz Canada as the case proceeds.

II. STATEMENT OF RELEVANT PROCEEDINGS

This case, based on an Abbreviated New Drug Application under the Hatch Waxman Act, involves a claim of patent infringement on patents relating to compound known as dexmedetomidine. (D.E. 1, Complaint ¶¶ 32-47.) Dexmedetomidine is the active molecule in a prior art mixture known as medetomidine, which was developed as a sedative before the filing of the patents in suit. The patents in the case are U.S. Patent Nos. 4,910,214 (the “’214 Patent”), which relates to dexmedetomidine and its use as a sedative, and 6,716,867 (the “’867 Patent”), which relates to the particular use of dexmedetomidine in an “intensive care” setting, with the result that patients are “arousable and orientated” after treatment. (D.E. 95, Mooney Decl. Exs. 2 & 3.)

Plaintiffs are Orion Corporation, the successor to the company that developed medetomidine, and Hospira Inc., the successor to Abbott Laboratories, the company that originally licensed dexmedetomidine for human use in the United States. (D.E. 1, Complaint ¶¶ 1-2, 4.) The original defendants to the case were Sandoz Inc. and Sandoz International GmbH. (D.E. 1, Complaint ¶¶ 1-2.) On May 17, 2010, Plaintiffs added Sandoz Canada to the action. (D.E. 55, Amended Complaint.) Sandoz Canada answered the complaint on July 1, 2010, and Plaintiffs answered Sandoz Canada’s counterclaims on July 22, 2010. (D.E. 72, Sandoz Canada’s Answer, Affirmative Defenses, and Counterclaims to Plaintiffs’ Amended Complaint; D.E. 76, Answer to Counterclaims of Sandoz Canada.) Sandoz Canada sought to negotiate a schedule with Plaintiffs for the service of contentions, but Plaintiffs refused to negotiate or agree to a schedule, and Sandoz Canada served its contentions on August 16 and August 27. (D.E. 87, Aug. 10, 2010, Letter from Defendants’ Counsel at 1; D.E. 95, Mooney Decl. Exs. 8-11; Mooney

Decl. Ex. 25 (Exhibits 7 & 10).) At about the same time, Sandoz Inc. provided Plaintiffs with proposed amended contentions that mirrored Sandoz Canada's contentions, and asked Plaintiffs to consent to their service. (D.E. 95, Mooney Decl. Exs. 12 & 13.) Plaintiffs again declined, and asked Magistrate Judge Bongiovanni to deny both Sandoz Canada and Sandoz Inc. the right to serve contentions. (D.E. 95, Mooney Decl. Ex. 26.) The parties submitted briefs and supporting declarations to the Magistrate Judge to consider. (See D.E. 95, D.E. 96, D.E. 98, D.E. 109, and D.E. 112.)

On October 21, 2010, Magistrate Judge Bongiovanni confirmed that Sandoz Canada could serve contentions as of right, but advised that Sandoz Inc. would need to produce a witness at a hearing to testify concerning its diligence. (D.E. 130, Transcript of November 16, 2010 Telephone Conference at 3-5.) On October 29, Sandoz Inc. informed the Court that the only witnesses who could testify would be trial counsel, which it believed would threaten the work product doctrine and the attorney-client privilege. (D.E. 123, Oct. 29, 2010 Letter from Defendants' Counsel at 1-2.) Sandoz Inc. accordingly asked the Court to reconsider that directive, or in the alternative, to allow Sandoz Inc. to simply join Sandoz Canada's contentions. (*Id.*) On November 16, at a conference, the Court offered Sandoz Inc. the choice of relying on Sandoz Canada's contentions, or providing a witness on diligence for cross-examination. (D.E. 130, Transcript of November 16, 2010 Telephone Conference at 3-5, 7-8, 10.)

Sandoz Inc. stated that it would rely on Sandoz Canada's contentions. However, on December 16, at Plaintiffs' request, the Court clarified its statements on the record to hold that Sandoz Inc. cannot rely on Sandoz Canada's contentions *during* the case, but only can argue collateral estoppel or res judicata at the *end* of the case. (Letter Order at 1.) This order

effectively denied Sandoz Inc.'s motion to amend its contentions or to join Sandoz Canada's contentions.

Claim construction in the case is fully briefed. Fact discovery ends on January 14, and expert discovery will begin with opening reports to be served on February 4. (D.E. 91, Stipulation Regarding Proposed Schedule at 2.) The 30-month stay in this case expires at the end of January 2012, and a trial date has not been set. (*Id.*)

III. THE PROPOSED AMENDED CONTENTIONS

Sandoz Inc.'s proposed amended contentions relate to three basic areas: (1) invalidity of the '214 Patent in view of evidence produced by Plaintiffs that refutes the claims of patentability Plaintiffs made during prosecution; (2) invalidity of the '867 Patent in view of references and studies sponsored by Plaintiffs; and (3) non-infringement of the '867 Patent based on testimony of Plaintiffs' expert during claim construction.

Invalidity of the '214 Patent. Sandoz Inc.'s initial contentions showed that the '214 Patent, which claimed dexmedetomidine and certain pharmaceutical compositions and methods for its use, was invalid because

- medetomidine, a well-known sedative, was known to be comprised of two forms, one of which was dexmedetomidine (D.E. 95, Mooney Decl. Ex. 5 at 3-7);
- it would be expected that one form of medetomidine would be more active than the other (*Id.*); and
- separating medetomidine into its components was obvious to try using known techniques (*Id.*).

These were exactly the conclusions reached by the PTO. (D.E. 109, Mooney Decl. Ex. 1.)

Plaintiffs overcame the PTO's rejections on this ground by arguing that the activity of dexmedetomidine was much better than would be expected and that the "surprising activity" was "particularly noticeable with respect to the α_2 - α_1 -selectivity ratio." (D.E. 109, Mooney Decl. Ex.

2 at 3.) That is, Plaintiffs argued that dexmedetomidine was surprisingly more selective for a particular kind of cell receptor – α_2 receptor – as compared to the α_1 receptor. Plaintiffs argued to the PTO that the α_2 - α_1 -selectivity ratio of dexmedetomidine was 45849 compared to 5060 for medetomidine – different by a factor of nine –and that this “surprising” result was allegedly “completely unexpected and could not be predicted.” (*Id.* at 3-4) This selectivity data is contained in “Table 2” of the ’214 Patent. Sandoz Inc.’s Preliminary Invalidity Contentions showed that the results of Table 2 were facially flawed and incorrect based on other published data. (D.E. 95, Mooney Decl. Ex. 5 at 7-8.) In light of that fact, the alleged “unexpected results” associated with the compound cannot be shown, and the PTO’s initial conclusions of obviousness should stand. (*Id.*)

[REDACTED].

Invalidity of the ’867 Patent. Sandoz Inc.’s initial contentions as to the ’867 Patent similarly show that the uses of dexmedetomidine claimed in that patent would have been obvious. (D.E. 95, Mooney Decl. Ex. 5 at 11-22.) Sandoz Inc.’s initial contentions show that dexmedetomidine was known to be similar to clonidine, and that the use of both in perioperative settings (before, during, and after surgery) to achieve variable states of sedation was also well known. (*Id.*)

Sandoz Inc.’s amended contentions expand on this analysis, primarily based on citations to articles by Dr. Talke, in 1995 and 1997. (*See* D.E. 95, Mooney Decl. Ex. 13 at 20-43; D.E. 95, Mooney Decl. Exs. 19 & 20.) Those studies were identified after Sandoz Inc.’s initial contentions were served, and addressed what the prior art cited originally by Sandoz Inc. made clear, *i.e.*, that particular sedative effects of dexmedetomidine could be achieved in a clinical

intensive care setting, and that particular dosages could be determined to achieve those effects. (*Id.*) [REDACTED].

Non-infringement of the '867 Patent. Sandoz Inc. also seeks to amend its contentions based on testimony of Plaintiffs' expert during his deposition on claim construction on July 6, 2010. [REDACTED].

IV. ARGUMENT: DENYING SANDOZ INC. LEAVE TO AMEND ITS CONTENTIONS WAS CLEAR ERROR AND CONTRARY TO LAW

A. The Standard of Review

Local Rule 7.1 sets forth the framework for appeal from a Magistrate Judge's order. "Any party may appeal from a Magistrate Judge's determination of a non-dispositive matter within 14 days after the party has been served with a copy of the Magistrate Judge's order, unless a motion for re-argument of the matter pursuant to L. Civ. R. 7.1(i) has been timely filed and served, in which case the time to appeal will begin to run when the parties are served with a copy of the Magistrate Judge's order rendering a determination on the merits of such a motion." L. Civ. R. 72.1(c)(1)(A). "A Judge shall consider the appeal and ... set aside any portion of the Magistrate Judge's order found to be clearly erroneous or contrary to law." *Id.*

A magistrate judge's order is clearly erroneous "when although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *Dome Petroleum Ltd. v. Employers Mut. Liab. Ins. Co. of Wis.*, 131 F.R.D. 63, 65 (D.N.J. 1990) (*quoting United States v. Gypsum Co.*, 333 U.S. 354, 395 (1948)). To be contrary to law, a magistrate judge's order must have "misinterpreted or misapplied applicable law." *Gunter v. Ridgewood Energy Corp.*, 32 F. Supp. 2d 162, 164 (D.N.J. 1998).

Sandoz Inc. respectfully submits that under these standards, the Letter Order should be reversed as (a) clearly erroneous and contrary to law because Plaintiffs have failed to show prejudice arising from the proposed amendments; (b) clearly erroneous because efficiency, fairness, and judicial economy compel a finding that Sandoz Inc. should be allowed to rely on Sandoz Canada's contentions; and (c) contrary to law in that it required Sandoz Inc. to risk waiver of its work product protections by producing attorneys of its trial firm to testify at a hearing as to diligence in identifying grounds for Sandoz Inc.'s defense.

B. The Conclusion that Sandoz Inc. Is Not Entitled to Amend Its Contentions Was Clearly Erroneous and Contrary to Law

Granting or denying leave to amend contentions is determined based on a consideration of (1) the importance and relevance of the proposed amendment, (2) whether the moving party has unduly delayed seeking leave to amend, and (3) whether and the opposing party will be unfairly prejudiced by the amendment, including whether a continuance of discovery would mitigate any prejudice. *See, e.g., TFH Publ'ns., Inc. v. Doskocil Mfg. Co.*, 705 F. Supp. 2d 361, 365-66 (D.N.J. 2010); *Arbitron, Inc. v. Int'l Demographics Inc.*, No. 2:06-CV-434 (TJW), 2008 U.S. Dist. LEXIS 87345, at *3-4 (E.D. Tex. Oct. 29, 2008).

By resolving the issue of Sandoz Inc.'s right to amend its contentions based on whether or not it could participate in an evidentiary hearing as to diligence without waiving its work product protections, the Letter Order did not apply the standards set forth in the Local Rules or in the decisions of this Court. Rather, those decisions establish that once a showing of diligence has been made, if Plaintiffs cannot establish prejudice, the amendments should be allowed. *See TFH Publ'ns.*, 705 F.Supp.2d at 367. That is the case here.

1. Sandoz Inc. Acted Diligently In Serving Its Amended Contentions

On or about April 22, 2010, Sandoz Inc. and Plaintiffs exchanged proposed amended pleadings. Plaintiffs proposed to add Sandoz Canada as a new party to the case, which would require Sandoz Canada to serve invalidity and non-infringement contentions after it was joined. L. Pat. R. 3.3. [REDACTED].

In light of the state of the pleadings and the need for contentions to be served by Sandoz Canada, Sandoz Inc. prepared to follow the schedule for amending contentions that was expected to be set for the service of contentions as of right from the newly added Sandoz Canada. However, by early August, it became clear that Plaintiffs would not agree that Sandoz Canada had a right to serve contentions, and that the Court's assistance would be required. Sandoz Inc., accordingly, provided Plaintiffs with amended contentions that mirrored those served by Sandoz Canada as of right at or about the time Sandoz Canada's contentions were served.

As set forth in more detail in the Declaration of Kyle Mooney (D.E. 95, Mooney Decl. ¶¶ 26-30), Sandoz Inc. learned of the documents and references only after its initial contentions were served, and not long before it became apparent that Sandoz Canada would be added to the case and would be serving its own initial contentions. Sandoz Inc. then served its amendments at the point in the case where they would cause the least disruption – when Sandoz Canada's contentions were served as of right. Moreover, at that time, no fact depositions had yet been conducted and expert discovery on merits issues was months away. In light of the need for contentions by Sandoz Canada, a battle over Sandoz Inc.'s contentions then would have been wasteful and unnecessary. The Mooney Declaration establishes more than a prima facie case of diligence under the circumstances.

Only Plaintiffs' refusal to agree to the efficient result has led to the current procedural posture – months of briefing over Sandoz Inc.'s contentions even though the same references and

documents will be indisputably in the case, the likelihood of two sets of contentions litigated in the case going forward, and the possibility of further briefing and delay after judgment before Plaintiffs will accept that it applies to them. Sandoz Inc. sought to avoid this by serving contentions along with Sandoz Canada, and acted diligently in doing so.

2. Plaintiffs Will Not Be Unfairly Prejudiced By Sandoz Inc.'s Amendments

It is undisputed that Plaintiffs will be litigating these very same claims of invalidity and unenforceability, on the merits, as asserted by Sandoz Canada. For that reason alone, Plaintiffs cannot claim prejudice from the amendments at issue.

But even apart from that fact, Plaintiffs have no conceivable prejudice. Sandoz Inc.'s proposed Amended Invalidity Contentions are based on the same scientific principles and concepts as its Preliminary Invalidity Contentions; the amended contentions, therefore, "do not raise new issues but instead merely supplement [Sandoz Inc.'s] initial contentions." *Golden Hour Data Sys., Inc. v. Health Servs Integration, Inc.*, No. C06-7477 SI, 2008 U.S. Dist. LEXIS 75495, at *13 (N.D. Cal. July 1, 2008), *see also TFH Publ'ns*, 705 F. Supp. 2d at 363-64. For the '214 Patent, Sandoz Inc.'s Preliminary Contentions showed that Plaintiffs' "Table 2" is unreliable; the amended invalidity contentions provide additional, contemporaneous documentation and explanation of that fact. Likewise, for the '867 Patent, the proposed amended invalidity contentions add additional support for the proposition that dexmedetomidine and the drugs in its class were known to have the "arousable and orientated" effect touted by the patent, and that it was known to be used in intensive care settings, as well as additional support that the dosing Plaintiffs' claim was obvious. These elements were shown or suggested by several prior art references in the Preliminary Contentions; the proposed amended contentions cite Talke 1995, which contains many of these disclosures in a single reference.

The only grounds of prejudice Plaintiffs advanced in briefing before the Magistrate Judge was that certain terms implicated by the assertion of Talke 1995 might need construction. (D.E. 98, Plaintiffs' Brief in Support of Their Request to Preclude Sandoz Inc.'s and Sandoz Canada's Proposed Invalidity and Non-Infringement Contentions at 16-18.) However, this was shown to be empty rhetoric when Plaintiffs refused to even respond to or discuss to Defendants' proposed construction of those terms in early October 2010. (D.E. 125, Nov. 8, 2010, Letter from Defendants at 2 n.1.) To this day, Plaintiffs still have not responded to Defendants' proposed constructions or sought supplemental claim construction briefing.

[REDACTED]. *See Avago Techs. Gen. IP PTE Ltd. v. Elan Microelectronics Corp.*, No. C04-05385 JW (HRL), 2007 U.S. Dist. LEXIS 39543, at *6 (N.D. Cal. May 17, 2007). Plaintiffs have also had ample notice—in some cases as of no later than April 22, 2010, the date that Sandoz Inc. provided its proposed Amended Answer and Counterclaims to Plaintiffs' Complaint—that Sandoz Inc. intended to rely on a number of the above-mentioned prior art references. (D.E. 95; Mooney Decl. Ex. 23, Counterclaims ¶¶ 23-25, 30-31, 58-68; *see also* D.E. 49, Stipulated Order; D.E. 62, Answer to Amended Complaint ¶¶ 43-53.) Sandoz Inc. certainly does not seek to avoid an adverse ruling or preclude adequate discovery on a last-minute new theory. *See Yodlee, Inc. v. Cashedge, Inc.*, No. C05-01550 SI, 2007 U.S. Dist. LEXIS 39564, at *5 (N.D. Cal. May 17, 2007). Finally, Sandoz Inc.'s amendments would not delay resolution of the case or necessitate a continuation of discovery. *Cf. King Pharms., Inc. v. Sandoz Inc.*, No. 08-5974 (GEB), 2010 U.S. Dist. LEXIS 50163, at *13-14 (D.N.J. May 19, 2010).

As Sandoz Inc. has made a prima facie showing of diligence, and Plaintiffs cannot show any prejudice whatsoever, Sandoz Inc.'s contentions should be allowed.

C. The Decision Not To Allow Sandoz Inc. to Rely on Sandoz Canada's Contentions Was Clearly Erroneous

Sandoz Inc. sought, in the alternative, to join Sandoz Canada's contentions, which are indisputably permissible. On these facts, the Magistrate Judge's decision not to allow Sandoz Inc. to rely on Sandoz Canada's contentions was clearly erroneous.

Sandoz Inc. has offered to join the contentions of Sandoz Canada for all purposes, and not proceed on separate or independent contentions – a result which would narrow the issues to be addressed by the Court and increase certainty for all parties. Plaintiffs will already be litigating the theories of invalidity and non-infringement of the Patents-In-Suit that Sandoz Canada has asserted. Requiring Sandoz Inc. to rely on its preliminary contentions alone, alongside the separate and more detailed contentions of Sandoz Canada will only multiply the proceedings to the detriment of all of the litigants and the Court. Meanwhile, it forces Sandoz Inc. to proceed through the entire case with the threat that Plaintiffs will seek to avoid an ultimate judgment until issues of res judicata and collateral estoppel are briefed at the conclusion of the trial.

While it is the case that if found invalid, Plaintiffs' patents are invalid as to Sandoz Inc. and Sandoz Canada alike under *Blonder-Tongue*, Plaintiffs have already stated that they will oppose that relief at the end of the action. Sandoz Inc. will win that dispute. *See Blonder-Tongue Lab., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313 (1971). However, Plaintiffs' position will give rise to needless delay. The purpose of ANDA litigation is to provide certainty to the parties as to whether a generic product will be allowed to launch. The ruling below leads to exactly the opposite result, and does not advance the expeditious or fair resolution of this case on the merits.

D. The Letter Order Was Contrary to Law Because It Failed to Resolve the Dispute on the Merits and Sandoz Inc. Is Entitled to Work Product Protection over Its Attorneys' Mental Impressions

Finally, the Letter Order was improvidently issued because it penalized Sandoz Inc. for asserting work-product privilege instead of resolving the dispute before the Court on the merits. The ruling below did not consider Sandoz Inc.'s proposed amendments on their own merits, did not address the specific references and documents at issue, and did not address the separate invalidity and non-infringement positions cited. Nor did it consider whether less intrusive means existed to provide additional information if the Court required – without risking waiver of trial counsel's opinion work product and strategies.

Under Rule 26, opinion work product and trial strategy must be protected from disclosure. Fed. R. Civ. P. 26(b)(3)(B). Sandoz Inc. explained that the new prior art references that it identified were discovered by litigation counsel, either through additional research or through review of Plaintiffs' document production. Likewise, the confidential documents discovered through review of Plaintiffs' production could only be found by litigation counsel. Trial counsel's review and analysis of Plaintiffs' documents, and its continuing prior art investigation, is necessarily and intrinsically related to its mental impressions and legal theories, which should be protected from disclosure. *See, e.g., In re Seagate Tech. LLC*, 497 F.3d 1360, 1373-74 (Fed. Cir. 2007) (discussing importance of protecting attorney mental impressions and legal theories) (citing *Hickman v. Taylor*, 329 U.S. 495, 510-11 (1947)); *see also Sporck v. Peil*, 759 F.2d 312, 314-17 (3d Cir. 1985) (holding that the selection and compilation of documents to prepare a witness for a deposition falls into the "highly-protected category of opinion work product").

Rather than penalizing Sandoz Inc. for seeking to protect its work product, the Letter Order should have resolved the issue on the merits based on Sandoz Inc.'s prima face showing of

diligence and Plaintiffs' comparative absence of prejudice, or sought, as have many other cases, additional information by briefing, argument, or declaration, which would avoid the threat to the work product protection raised by the ruling below. *See Streak Prods., Inc. v. Antec, Inc.*, No. 09-04255 RS (HRL), 2010 U.S. Dist. LEXIS 97613, at *4-11 (N.D. Cal. Sept. 8, 2010) (holding, based on supplemental declarations submitted upon order of the court, that defendants had demonstrated diligence and good cause to amend their invalidity contentions); *Acco Brands, Inc. v. PC Guardian Anti-Theft Prods., Inc.*, No. 04-03526 SI, 2008 U.S. Dist. LEXIS 88142, at *7-8 (N.D. Cal. May 22, 2008) (granting motion to amend invalidity contentions where declaration submitted by defendants confirmed that they had been diligent and plaintiff failed to demonstrate any prejudice).

CONCLUSION

Sandoz Inc. respectfully requests that the Court reverse that portion of the Letter Order precluding Sandoz Inc. from amending its contentions to mirror those served by Sandoz Canada.

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